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International Regulation of Emerging Technologies:

Global Ideologies and Local Headaches

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This paper begins to address the international regulation of emerging technologies taking an approach that includes the co-production of technologies and the nature of wicked problems. Both the development of technologies over time, the role of science in regulation, and results from case studies in the regulation of biotechnologies are discusses. Biotechnology, nanotechnology and synthetic biology receive the most attention.

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Table of Contents

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In Anthropocene or in Chuthulucene

This essay considers international regulation of emerging technologies at dawn of the Chutullucene[1] and starts the enterprise of reengineering regulatory and governance concepts to take into account concepts of knowledge co-production[2] and wicked complexity.[3] If we are to take the advice of Donna Haraway, "we must address intense, systemic urgencies. "[4] Is climate change one of these systemic urgencies? What role has technology, more appropriately, what role will technologies play and what has our understanding of past technologies and their regulation played in our ability to produce regulation, international or otherwise, that is appropriate? One working principle is that appropriateness of regulation and governance is indicated by the ability to bring out desired outcomes, that is effectiveness. This in turn implies that regulation and governance must be informed by corresponding values as organising principles.

One of the many claims being made in academic and non-academic narratives, it is that synthetic biology, at least in the form of iGEM (international genetically engineered machines),[5] is that one enabler in the so-called third industrial revolution.[6] However this third industrial revolution is as cluttered with claims to its enablers as it is to its very happening. Some propose that we are seeing with the emergence of artificial intelligence and the convergence of physical, mechanical, digital, chemical and biological technologies, is the fourth industrial revolution.[7] It's not complicated, it is complex and muddled.

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[1] Donna Haraway, 'Anthropocene, Capitalocene, Plantationocene, Chthulucene: Making Kin', *Environmental Humanities* 6 (2015): 159–65. Note the various proposed names for the present epoch are subjects of considerable debate, and in itself point to the complex nature of the pluratiy in which we live.

[2] Sheila Jasanoff and Sang-Hyun Kim, eds., *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power* (University of Chicago Press, 2015), 3, 6–7, 14, 22, 326, 332.

[3] For an introduction to the nature of 'wicked complexity' as opposed to 'static complexity' see: Braden R. Allenby and Daniel Sarewitz, *The Techno-Human Condition* (Cambridge, Mass.: The MIT Press, 2013), 109.

[4] Haraway, 'Anthropocene, Capitalocene, Plantationocene, Chthulucene: Making Kin'.

[5] Manuel Porcar and Juli Peretó, *Synthetic Biology: From iGEM to the Artificial Cell* (Springer, 2014); Christina D Smolke, 'Building outside of the Box: iGEM and the BioBricks Foundation', *Nat Biotech* 27, no. 12 (December 2009): 1099–1102; Rudolph Mitchell, Yehudit Judy Dori, and Natalie H. Kuldell, 'Experiential Engineering Through iGEM-An Undergraduate Summer Competition in Synthetic Biology', *Journal of Science Education and Technology* 20 (2011): 156–60.

[6] George M. Church and Ed Regis, *Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves* (Basic Books, 2012), 179.

[7] Klaus Schwab, *The Fourth Industrial Revolution* (World Economic Forum, 2016); M. Waidner and M. Kasper, 'Security in Industrie 4.0 - Challenges and Solutions for the Fourth Industrial Revolution', Dresden, in *Design, Automation Test in Europe Conference Exhibition* (Dresden: IEEE, 2016), 1303–8; Andrew D. Maynard, 'Navigating

This paper begins to address the role and prospects of international regulation of emerging technologies given by the contexts provided by a global economy, the aspirations of sustainable development, and the desire to respect human rights as organising principles. To do this the complex relationship between the worlds of science and technology and that of law need to be revisited with the hope of recognizing past failures and potential venues for action. After setting the technologies-context and introducing the concept of co-production, the case of biotechnology is taken up and discussed in light of its newest developments in synthetic biology. A brief perusal through what international regulation of technologies in general, and WTO law in particular offer in dealing with the advancing edge of technology finds the system wanting. While there are many proposals for global governance of technologies, none seem to lend themselves to the aspirations of sustainable development and an increasing expectation that whatever happens in technology or economics be inclusive.

Technologies

Technology is not one discipline; it is neither monolithic nor homogeneous. A plurality of technologies ranging from the molecular to the planetary have evolved over time and are emerging across all scientific and technical disciplines. Above all, technology is normative, not a panacea.[8] One can also say that technologies are artefactual, and located in time and space. To contextualize international economic law and how it treats the regulation of technology in time and space calls for an understanding of the interfaces between law and technology within our actuality. Whether we want to consider our actuality as modern post-modern, or accelerationist may affect the assumptions to be made about technology's role in society which in turn yield different results as to the regulatory options available for consideration. In this essay we use the idea of modernity, and leave a post-modernist approach for a later occasion. Already the bridging of modernity – and technology is a task that leave most looking for easier terrain to explore.

The nature of our actuality is marked by political, legal, moral, technological, and scientific discourses around global climate change, human rights and dignity (terrorism and war, migration, globalisation), plus sustainability, all with an unprecedented acceleration of developments that strain and stress notions of legitimacy, legal concepts, established regulatory agencies and mankind's own understanding of itself.

First, the evolution of our understanding of technology directs us to come to grips with what technology is and to try to understand it within the globalisation context. Broadly speaking technology is the application of scientific knowledge for practical purposes, especially in

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the Fourth Industrial Revolution', *Nature Nanotechnology* 10, no. 12 (December 2015): 1005–6.

[8] Hans Radder, 'Why Technologies Are Inherently Normative', in *Philosophy of Technology and Engineering Sciences*, ed. Anthonie Meijers, Handbook of the Philosophy of Science (Amsterdam: North-Holland, 2009), 887–921, http://www.sciencedirect.com/science/article/pii/B9780444516671500379.

industry. Such a definition, even if taken from the dictionary, is coloured by instrumental rationality. For regulatory purposes technology has been treated as an exogenous object that can be controlled in a predefined way and that is too pedestrian for proper consideration by the high priests of the social sciences. This antiquated idea assumes that (ubiquitous) control (of technology) is possible. It also overlooks unintended consequences (surprises) and emergent phenomena.

A systemic approach to technology regulation that addresses its updated contemporary ubiquity, diversity and uncertainties appears unexplored. Technology regulation can be applied in many different social contexts – production, consumption, use, disposal, etc. – that generate plenty of legal questions and require a multitude of carefully differentiated considerations with respect to the life-cycle of the specific technology, and the production-chain of that industry. Technology's normativity has often been ignored and a range of attitudes and values have been attributed to it depending on whatever ideology or theory permeated the thinking of scholars and regulators. In fact, pervasiveness and success of modern technology means that technological decisions increasingly affect social life. That is, due to this pervasiveness, intensity, and interwoven character of the fibres of society and technology, "one can draw diametrically opposed conclusions: either politics becomes another branch of technology, or technology is recognized as political".[9]

Co-production

We can generally agree that an apparent acceleration in technological development creates challenges to existing practices and normative understanding that are yet to be identified be it in quality, quantity or scope. That is, uncertainty is what we need to cope with in a world marked by increasingly wicked problems. Two different historicised surveys of technology systems can serve as guiding posts towards trying to gain perspective. The first one dates from 1946, and the second from 2013. Lewis Mumford's 1946 classification[10] is separated in time by half-century from that of Allenby and Sarewitz[11] and while sinning in the direction of reductionism, they can later be analysed through the prism of critical theory such as that offered by Feenberg.[12]

Mumford distinguishes three successive main technology phases: eotechnic, paleotechnic, and neotechnic each marked by a set of distinct inventions. The eotechnic or early phase of technics stretches roughly from 1000 to 1750 when "invention and experimental adaptation

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[9] Andrew Feenberg, *Questioning Technology* (Routledge, 2012), 2.
[10] Lewis Mumford, *Technics and Civilization* (London: Georg Routledge & Sons, Ltd., 1946).
[11] Allenby and Sarewitz, *The Techno-Human Condition*.
[12] Feenberg, *Questioning Technology*; Andrew Feenberg, *Between Reason and Experience: Essays in Technology and Modernity* (MIT Press, 2010); Tyler J. Veak, *Democratizing Technology: Andrew Feenberg's Critical Theory of Technology* (SUNY Press, 2006); Andrew Feenberg, *Transforming Technology : A Critical Theory Revisited: A Critical Theory Revisited* (Oxford University Press, USA, 2002).

went on at a slowly accelerating pace" and new sources of energy were developed.[13] Once equipped with mechanical clocks, telescopes, cheap paper, printing presses, magnetic compasses from the eotechnic the next phase – the paleotechnic – saw the invention of the steam engine and the beginning of the destruction of the environment, and the degradation of the worker all in favour in the doctrine of progress in what we are accustomed to call the first industrial revolution from ca. 1760 to 1820, which is also often referred to as the first industrial revolution. The neotechnic phase, the one during which Mumford wrote his observations, is in his words "a definite physical and social complex" that began in 1832 with the "perfection of the water-turbine by Fourneyron[14] and is marked by the conquest of new forms of energy, namely electricity.[15] Mumford's distinctions are useful as they illustrate the cumulative nature of technology, and its inextricability from the social condition of man from a linear historical perspective that also demonstrates the so-called acceleration of the pace of invention. Once electricity and the steam engine enter our sociotechnical world, technologies multiply in every possible direction into every aspect of human activity.

The approach developed by Allenby and Sarewitz distinguish three levels of technology designated I, II, and III. This taxonomy permits a clearer structural understanding of the differences between toasters and nuclear weapons perspective.[16]At level I, technology's intention and effect are at hand. For example, toasters reliably and safely deliver toasted bread or airplanes carry passengers from point A to point B. At level I of technology, systemic complexity is forgotten. Level II, in the Allenby-Sarewitz model we encounter the systemic complexity around air travel (or the production of toasters or automobiles). That is, to stay with Allenby-Sarewitz model, at level II we have the air transportation system embodied with "the irrationality, dysfunction and insane price system, the absurd inefficiency of its boarding and security processes, the continual delays, and …".[17] Looking at technology as a whole in level II, we soon discern the first contours of a system and the emergence of the lock-in phenomena concurrently with a level II ambivalence and ambiguity that is accompanied by a reliable level I technology. The Allenby-Sarewitz level III pattern in this technology taxonomy is perhaps easier to recognize in highly networked transportation systems (still, we can also see in energy production systems, telecommunications, agriculture, textiles) such as those of transportation either by air or land. At level III we observe the co-evolution of "significant changes in environmental and resource systems; mass-market consumer capitalism; individual credit; behavioural and aesthetic subcultures and stereotypes; with oil spills; with opportunities for, and a sense of, extraordinary human freedom, especially for women… ".[18] Mumford, Allenby and Sarewitz, in spite of the seventy years between their observations both point to the unequivocal co-production of technology or the "constant intertwining of the

[13] Mumford, *Technics and Civilization*, 111–23.
[14] Dietrich Eckardt, *Gas Turbine Powerhouse: The Development of the Power Generation Gas Turbine at BBC - ABB - Alstom* (Walter de Gruyter GmbH & Co KG, 2014), 49. Benoit Fourneyron (1802-1867) was a French engineer educated at the École Nationale des Mines de Saint-Etiénne .
[15] Mumford, *Technics and Civilization*, 212ff.
[16] Allenby and Sarewitz, *The Techno-Human Condition*, 36.
[17] Ibid., 37.
[18] Ibid., 39.

cognitive, the material, the social and the normative".[19] Co-production of natural and social orders means that the ways in which we represent the world are inseparable from the ways that we choose to live in it.[20] That is, explanatory power is gained by thinking of natural and social orders together where both nature and society are inseparable.[21]

Science at the Service of Technologies

The common understanding is that when evaluating a technology's *effectiveness* and *safety* the usual course of action is to make recourse to science in assessing the technology's effectiveness and safety. There are then two tasks that science ought to accomplish: fact finding and deciding what is safe and effective. The first task is the one that traditional – normal science – is best equipped to do within its reductionist walls. The second task is uncomfortable for scientists – post normal science – involves the acknowledged addition of values.[22] However it is that last task that attempts to connect the dots of uncertainty by appealing to values that could bear the mark of a least common denominator. What the results are, does depend on the values applied. It is however not clear that it is possible to find that least common denominator for all. Or, to put in other words "the authority of science is not a foundation for factual enlightenment but an ideological foundation for authoritarian policy prescriptions that might otherwise be difficult to implement" in world of wicked problems, "more likely to deliver surprises than solutions."[23]

Biotechnology revisited in the Chuthulucene

The transition from biotechnology to synthetic biology has been evolutionary, and in keeping with the general development allowed by academic and economic freedoms. Still while there are many commonalities, there are also marked differences. The most radical difference being that of the possibilities enabled by the discovery of a group of genes that allow for very precise engineering of genomes.[24]

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[19] Sheila Jasanoff, 'The Idiom of Co-Production', in *States of Knowledge : The Co-Production of Science and Social Order*, ed. Sheila Jasanoff, International Library of Sociology (London: Routledge, 2004), 1–12.
[20] Ibid.
[21] Ibid.
[22] Silvio O. Funtowicz and Jerome R. Ravetz, 'Science for the Post-Normal Age', *Futures* 25, no. 7 (September 1993): 739–55; Jerry Ravetz, 'The Post-Normal Science of Precaution', *Futures* 36, no. 3 (April 2004): 347–57.
[23] Allenby and Sarewitz, *The Techno-Human Condition*, 122.
[24] Simon N. Waddington et al., 'A Broad Overview and Review of CRISPR-Cas Technology and Stem Cells', *Current Stem Cell Reports* 2, no. 1 (11 February 2016): 9–20; Jacob S. Sherkow, 'CRISPR: Pursuit of Profit Poisons Collaboration', *Nature* 532, no. 7598 (13 April 2016): 172–73; Eric S. Lander, 'The Heroes of CRISPR', *Cell* 164, no. 1–2

The Global Ideologies

A recent review of 99 peer-reviewed journal articles published since 2004 on the social impacts of genetically modified (GM) crops in agriculture comes to the conclusion that the most commonly studied impact – economic – mainly report that there are benefits while other social impacts that are less studied present a more complex picture.[25]

Biotechnology has received detailed attention in international law , international relations, and the science and technology studies literature.[26] Briefly stated, differences of opinion and values between the United States and the European Union over the regulation of genetically modified organisms have resulted in a lack of cooperation and stark differences in regulatory standards and frameworks while the rest of the world muddles through.[27]

One view is that there is no perceived public crisis in biotechnology that created a specific regulatory moment as has been the case for other regulatory objects.[28] That may be so, and the differences may arise from a multitude of sources, and they may be endogenous or

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(14 January 2016): 18–28; Daniel Sarewitz, 'CRISPR: Science Can't Solve It', *Nature* 522, no. 7557 (23 June 2015): 413–14; David Cyranoski, 'CRISPR Tweak May Help Gene-Edited Crops Bypass Biosafety Regulation', *Nature*, 19 October 2015, http://www.nature.com/doifinder/10.1038/nature.2015.18590; Jennifer A. Doudna and Emmanuelle Charpentier, 'The New Frontier of Genome Engineering with CRISPR-Cas9', *Science* 346, no. 6213 (28 November 2014): 1258096.

[25] Klara Fischer et al., 'Social Impacts of GM Crops in Agriculture: A Systematic Literature Review', *Sustainability* 7, no. 7 (2 July 2015): 8598–8620.

[26] Thomas Bernauer, *Genes, Trade, And Regulation: The Seeds Of Conflict In Food Biotechnology* (Princeton University Press, 2003); Susette Biber-Klemm et al., 'Challenges of Biotechnology in International Trade Regulation', in *The Prospects of International Trade Regulation: From Fragmentation to Coherence*, ed. Thomas Cottier and Panagiotis Delimatsis (Cambridge ; New York: Cambridge University Press, 2011), 284–320; Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton, N.J: Princeton University Press, 2005); Mark A. Pollack and Gregory C. Shaffer, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (OUP Oxford, 2009); Daniel Wüger and Thomas Cottier, eds., *Genetic Engineering and the World Trade System*, World Trade Forum (Cambridge ; New York: Cambridge University Press, 2008).

[27] Pollack and Shaffer, *When Cooperation Fails*, 1–32.

[28] Michael Howlett and David Laycock, eds., *Regulating Next Generation Agri-Food Biotechnologies* (Routledge, 2013), 49–72; Michael Howlett and Joshua Newman, 'After "the Regulatory Moment" in Comparative Regulatory Studies: Modeling the Early Stages of Regulatory Life Cycles', *Journal of Comparative Policy Analysis: Research and Practice* 15, no. 2 (1 April 2013): 107–21.

exogenous.[29] The problem is an old one. What looks good in theory, encounters problems when put into practice, and the reality may be more complex than it was hoped for.

Academics, farmers, activists, multinational corporations, government officials all promote their views on the advantages of technology or its regulation, however when it comes to GM crops "the scientific data are often inconclusive or contradictory".[30] In 2013 a record of 175.2 million hectares of biotech crops were grown globally.[31] Meanwhile a bit of dust has started to accumulate on some of earlier texts on the international aspects of genetically modified organisms (GMO), and one wonders how these narratives compare with local farmer's realities.

The Local Headaches

Let's take the case of GM cotton which constitutes a large fraction of the total global production of all of GM crops. The estimate is that in the US more than 90 per cent of the planted cotton is 2014 was GM.[32] In Argentina the estimate is that it covers about 80-90 per cent of the area sown albeit with uncertified transgenic seed.[33]Briefly, there are three main types of GM cotton varieties based on two different genetic traits: one is resistant to the herbicide glyphosate (also known by Monsanto's trademark Roundup), another produces toxins that kill cotton bollworm. The tree types of GM cotton on the market are: one that is glyphosate resistant, one that produces the Bt toxin, and a third incorporating both traits. Over fifty different commercial GM cotton seeds have been approved. The seeds trade names and details are available in databases such as those maintained by the International Service for the Acquisition of Agri-Biotech Applications [34], GMO Compass.[35] The International Cotton Advisory Committee[36] provides statistics on world cotton production, consumption, trade, and serves as

[29] Michael Howlett and Andrea Mignone, 'Regulatory Lifecycles and Comparative Biotechnology Regulation', in *Regulating Next Generation Agri-Food Bio-Technologies*, ed. Michael Howlett and David Laycock (Routledge, 2013), 64.
[30] Natasha Gilbert, 'Case Studies: A Hard Look at GM Crops', *Nature* 497, no. 7447 (1 May 2013): 24–26.
[31] Clive James, 'Global Status of Commercialized Biotech/GM Crops: 2013 - ISAAA Brief 46-2013: Executive Summary', *International Service for the Acquisition of Agri-Biotech Applications*, 2014, http://www.isaaa.org/resources/publications/briefs/46/executivesummary/.
[32] http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx
[33] Maria-Eugenia Fazio et al., 'Local Realities for Transgenic Cotton', in *Regulating Technology: International Harmonization and Local Realities*, ed. Patrick Van Zwanenberg, Adrian Ely, and Adrian Smith (London ; Washington, DC: Earthscan, 2011), 73–98.
[34] http://www.isaaa.org/
[35] http://www.gmo-compass.org/
[36] https://www.icac.org/

a clearing house for technical information about cotton and cotton textiles; it also represents the international cotton industry before UN agencies and other international organizations.

In theory and in the laboratory, but also from an ideological point of view, great opportunities for better integration of conventional breeding and molecular biology to improve cultivars and herald a new age in cotton improvement seem promising.[37] It is claimed that 80% of global cotton production in 2012 was that from genetically modified seeds[38] The reality on the ground tells a different story.

In the global south, one study in the Chaco province in Argentina what was found was that only the 2 per cent of farmers with more than 200 hectares of land and producing 70 per cent of the cotton had both the means to buy certified transgenetic seed and both the knowledge and scale to maintain quality of successive multiplications of saved seed.[39] To add insult to injury, the '2 per cent farmers' are also adept at ignoring contracts that would bind them to take recommended measures to maintain the quality of the new seed and to delay development of pest resistance to the Bt toxin while the majority in the same region who obtain non-certified seeds in informal markets have neither the gins to delint the seeds nor the knowledge to ensure quality or make the best of what they.[40] That is, the majority of these Argentinian small cotton farmers get seeds of not only variable, but doubtful quality with transgenic and non-transgenic traits, and due to the lack of knowledge or mislabelling farmers end up with poor yields as may be case if a herbicide resistance is assumed when instead the non-certified seed is pesticide resistant. That is, these small cotton farmers are beyond the reach of the regulatory regime. In this case, the local regulatory agency – the Insituto Nacional de Semillas (INASE) – is practically incapable of asserting any oversight especially in informal markets, but also there where farmers ignore contractual obligations although their task is that of applying the Seed Law (Ley de Semillas Y Creaciones Fitogenéticas N° 20.247). The resulting situation is one where regulation of the technology fails at several levels beyond the international modalities that made it possible for the seed to enter the market. The interests of those whom the technology ought to benefit are left unattended by local and national governments. The rights, moral and ethical values recognized by international law are orphaned.

This situation also raises question of biosafety and biodiversity. The fact that uncontrolled GM seeds reach the informal markets without biosafety testing and approval, leaves open the

[37] Greg Constable et al., 'Cotton Breeding for Fiber Quality Improvement', in *Industrial Crops*, ed. Von Mark V. Cruz and David A. Dierig, Handbook of Plant Breeding 9 (Springer New York, 2015), 191–232, http://link.springer.com/chapter/10.1007/978-1-4939-1447-0_10.
[38] Ibid.
[39] Fazio et al., 'Local Realities for Transgenic Cotton'.
[40] Ibid.

question of "regulatory capacity to anticipate and diminish potential environmental impacts, or to assure international markets that exported products are what they purport to be".[41]

In the provinces of Hubei and Shandong in China the sociotechnical dynamics are different from those in the Chaco proving in Argentina, and correspondingly the regulatory failures are different. Using nationally representative panel data, Arza and van Zwanenberg analysed the economic impact of Bt cotton adoption and its sustainability, after 15 years of its commercialization in China. Consistent with its short-term impact, the study they showed that the economic benefit of Bt cotton did not diminish, but remained stable and continuous in China.[42] Their study that uses nationally representative data and focuses on the economic benefit of Bt cotton and its dynamics. "As shown in this paper, the first generation of cotton varieties with a single Bt gene still can effectively control the bollworm. Even though farmers in some countries have switched from unpatented and royalty fee cotton varieties with a single Bt gene to patented cotton varieties with stacked genes, rigorous analysis is needed to answer whether this switch is economical or a result caused by many factors ."[43]

The patterns described for "international transfer to and adaptation of genetically modified (GM) cotton in Argentina, and ask whether political bargaining between the technology owner, a multinational enterprise (MNE), and host country actors may have influenced upgrading" to GM crops. These authors suggest that "the MNE was able to use its exclusive capacity to upgrade GM cotton technologies as a negotiation tool to persuade host actors to change the rules that affected its multiple line of business in the country. This implies wider policy scope to encourage technology upgrading; host actors could negotiate over a wider range of aspects of interest to MNEs."[44]

That there many more problems to be addressed beyond the interests of multinational corporations ought to be evident. That is, "despite the widespread adoption of *Bt* crops and a continued increase in the area on which they are grown, there are still a number of unanswered questions associated with longer term agro-ecosystem interactions, for instance the impact of secondary pests."[45]

Meanwhile the situation is not optimal in the global north either even if the problems have a different character. In the US the annual statistics for 1992 to 2009 on cotton planted indicates that while the percentage of genetically modified cotton has increased to nearly 90 per cent, the average annual total herbicide application rate for cotton (mass per area) fails to show a

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[41] Ibid., 85.
[42] Valeria Arza and Patrick van Zwanenberg, 'The Politics of Technological Upgrading: International Transfer to and Adaptation of GM Cotton in Argentina', *World Development* 59 (July 2014): 521–34.
[43] Fangbin Qiao, 'Fifteen Years of Bt Cotton in China: The Economic Impact and Its Dynamics', *World Development* 70 (June 2015): 177–85.
[44] Arza and van Zwanenberg, 'The Politics of Technological Upgrading'.
[45] Rui Catarino et al., 'The Impact of Secondary Pests on Bacillus Thuringiensis (Bt) Crops', *Plant Biotechnology Journal* 13, no. 5 (1 June 2015): 601–12.

decrease although it would have been expected according to theory and rationale of introducing transgenetic traits.[46]

Regulation and Governance Dreamscapes

Nanotechnologies, like other proceeding technologies, have gotten much attention and a too large body of literature has been generated displaying a spectrum of views. There is some agreement that there are two main dangers. One is that a "blinkered adherence to science-driven and hierarchical decision-making approach" in regulation will ignore the values of the citizens who seek to influence regulation by some participative or other legitimizing mechanisms.[47] Another is that perceptions counter to current scientific understanding may have an undue or non-justifiable influence on regulatory decisions.[48] That is, balance is required, and social, regulatory and governance innovation is called upon to assure transparency, legitimacy and trust in the regulatory process.

"We have come to the point in synthetic biology where there are many lab-scale or proof-of-concept examples of chemically controlled systems useful to sense small molecules, treat disease, and produce commercially useful compounds. These systems have great potential, but more attention needs to be paid to their stability, efficacy, and safety."[49] (link to case studies where appropriate)

Gervais analysis uses a classification of technology that is interesting as an analytical tool, and relies mainly on the precautionary principle application to leave the emerging technology unregulated and pleads for a nimble regulatory approach (courts, regulatory agencies) when risks emerge.[50] This proposed approach ignores the nature of technology and co-production. (to be expanded)

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46 See Table 3 in: Richard H Coupe and Paul D Capel, 'Trends in Pesticide Use on Soybean, Corn and Cotton since the Introduction of Major Genetically Modified Crops in the United States', *Pest Management Science*, 1 August 2015, n/a-n/a.
47 Andrew D. Maynard, Diana M. Bowman, and Graeme A. Hodge, 'Conclusions: Triggers, Gaps, Risks and Trust', in *International Handbook on Regulating Nanotechnologies*, ed. Graeme A. Hodge, Diana M Bowman, and Andrew D. Maynard (Cheltenham, UK: Elgar, 2010), 573–86.
48 Ibid.
49 Tyler J Ford and Pamela A Silver, 'Synthetic Biology Expands Chemical Control of Microorganisms', *Current Opinion in Chemical Biology*, Synthetic biology • Synthetic biomolecules, 28 (October 2015): 20–28.
50 Daniel J. Gervais, 'The Regulation of Inchoate Technologies', *Houston Law Review* 47, no. 3 (18 November 2010): 665–705.

Harmonization presumes stable and widely shared goals. Develop. “How do harmonizing regulations impact on the opportunities for poorer communities in developing countries to effectively access new technologies, assure themselves of benefits, whilst guarding against risks? How do harmonizing regulations affect the capacity of poorer communities, local and national businesses, and national governments to develop locally appropriate forms of technology use? Do regulations enable environmentally sustainable and socially just technology development pathways appropriate to specific situations or do they hinder them?”[51]

Last but not least, there is the issue of what can WTO do to deal with emerging technologies. The verdict is that if an analysis (type) of the EU GM regulation in light of the WTO trade disputes is indeed legal, but it certainly has been costly.[52] Then when looked at in detail, while WTO and international law cannot really ease the burden of dealing with wicked regulatory and governance problems, a streamlining of its functions could be helpful is reducing of of the burdens. (to be developed, TBT is what is on the line, it is about standards after all).

[51] Compare Ely, Winter, Maynard, and Gervais (consider Feenberg) Adrian Ely, Patrick Van Zwanenberg, and Andrew Stirling, ‘Broadening out and Opening up Technology Assessment: Approaches to Enhance International Development, Co-Ordination and Democratisation’, *Research Policy* 43, no. 3 (April 2014): 505–18; Gerd Winter, ‘In Search for a Legal Framework for Synthetic Biology’, in *Synthetic Biology Analysed*, ed. Margret Engelhard, Ethics of Science and Technology Assessment 44 (Springer International Publishing, 2016), 171–211, http://link.springer.com/chapter/10.1007/978-3-319-25145-5_7; Gerd Winter, ‘The Regulation of Synthetic Biology by EU Law: Current State and Prospects’, in *Synthetic Biology*, ed. Bernd Giese et al., Risk Engineering (Springer International Publishing, 2015), 213–34, http://link.springer.com/chapter/10.1007/978-3-319-02783-8_11; B. Erickson, R. Singh, and P. Winters, ‘Synthetic Biology: Regulating Industry Uses of New Biotechnologies’, *Science* 333 (1 September 2011): 1254–56; Elen Stokes and Diana M. Bowman, ‘Looking Back to the Future of Regulating New Technologies: The Cases of Nanotechnologies and Synthetic Biology’, *European Journal of Risk Regulation* 2012 (2012): 235; Jennifer Kuzma and Todd Tanji, ‘Unpackaging Synthetic Biology: Identification of Oversight Policy Problems and Options’, *Regulation & Governance* 4 (1 February 2010): 92–112; Henry Miller Drew Kershen, ‘Will Overregulation In Europe Stymie Synthetic Biology? - Forbes’, *Forbes.com*, n.d.; Mithun Bantwal Rao et al., ‘Technological Mediation and Power: Postphenomenology, Critical Theory, and Autonomist Marxism’, *Philosophy & Technology* 28, no. 3 (September 2015): 449–74; Gregory Conko et al., ‘A Risk-Based Approach to the Regulation of Genetically Engineered Organisms’, *Nature Biotechnology* 34, no. 5 (May 2016): 493–503; Alexander Kelle, ‘Beyond Patchwork Precaution in the Dual-Use Governance of Synthetic Biology’, *Science and Engineering Ethics*, 26 May 2012.

[52] Maarten J. Punt and Justus Wesseler, ‘Legal But Costly: An Analysis of the EU GM Regulation in the Light of the WTO Trade Dispute Between the EU and the USA’, *The World Economy* 39, no. 1 (1 January 2016): 158–69.

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